DISTRICT OF COLUMBIA
OFFICE OF ADMINISTRATIVE HEARINGS
825 North Capitol Street, NE, Suite 4150
Washington, DC 20002-4210
Telephone: (202) 442-9094
Fax: (202) 442-4789

DISTRICT OF COLUMBIA DEPARTMENT OF HEALTH Petitioner, v. CVS PHARMACY Respondent.	Case No.: DH-I-07-D100273 DH-I-07-D100274 DH-I-07-D100279 DH-I-07-D100288 DH-I-07-D100291 DH-I-07-D100292 DH-I-08-D100282 DH-I-08-D100304 DH-I-08-D100305 DH-I-08-D100307 **(CONSOLIDATED)**

CONSOLIDATION ORDER/
FINAL ORDER FOR ALL "RETURN TO STOCK" VIOLATIONS CONTAINED IN EACH NOTICE OF INFRACTION CONSOLIDATED HEREIN/
FINAL ORDER DISMISSING DH-I-07-D100292

I. INTRODUCTION

The Government has served Respondent with ten Notices of Infraction ("NOI"), as reflected in the cases consolidated herein. While these NOIs involve different CVS pharmacies, these stores are owned by the same corporate entity and there is ultimately one Respondent - CVS. Additionally, there are common questions of law and fact in many, but not all, of the NOIs at issue. The parties believe that consolidation of these matters will prevent unnecessary cost and delay. Therefore, based on the consent of the parties and the entire record herein, I will consolidate these matters. OAH Rule 2819.

I will separate the issues raised in the NOIs into three groups: 1) the violations contained in NOIs D100273, D100279, D100291, D100282, D100304, and D100305, which, for the sake of convenience, the parties and I have labeled "Return to Stock" violations; 2) D100292, which is being dismissed with prejudice; and 3) any outstanding issues associated with the consolidated cases, which will be resolved in separate Final Orders. OAH 2919.3. The designation ("Return to Stock") will be explained below.

II. Return to Stock Violations (NOIs D100273, D100279, D100291, D100282, D100304, and D100305)

In these NOIs, the Government alleged that Respondent violated D.C. Code, 2001 Ed. § 47-2885.10(a)(3) by offering for sale misbranded drugs. Respondent filed pleas of Deny to each of these violations. The commonality of these NOIs is a CVS policy which governs all of Respondent's stores in the District of Columbia. After an evidentiary hearing was held concerning NOI D100273 on November 16, 2007, and post-trial briefing (the Government filed its brief on December 7, 2007, Respondent filed its brief on December 28, 2007, and the Government chose not to file a reply brief), all of these cases were stayed as the parties attempted to settle these matters. They were unsuccessful and I allowed both sides to submit additional evidence and arguments. Respondent filed its submission on April 25, 2008, the Government on May 8, 2008, and Respondent replied to the Government's submission on May 22, 2008.

The Government has been represented in all of these matters by Thomas Collier, Esq. Janis Jackson, Pharmacist, testified on behalf of the Government at the November 16, 2007, hearing. Respondent has been represented by Edward Krill, Esq., in all of these matters. Earl Ettienne, Senior Pharmacy Supervisor, appeared as corporate representative for Respondent.

During the November 16, 2007, hearing, I admitted into evidence the Government's exhibits 100-102, and Respondent's exhibits 200-205. There being no objection by the Government, I hereby admit into evidence Respondent's post-trial submissions as exhibits 206 – 210B. The parties have agreed that the evidence admitted during the November 16, 2007, hearing is demonstrative of the situation at all stores and may form the basis for my Findings of Fact and Conclusions of Law for all of the consolidated cases with a Return to Stock violation.

At the start of the November 16, 2007, hearing, Respondent argued that the alleged violation of offering for sale misbranded drugs should be dismissed on grounds of *res judicata* and/or collateral estoppel. Respondent's premise was that I had already ruled in an earlier case, under a fact pattern nearly identical to this case, that Respondent had not violated the then-cited regulations (D.C. Code, 2001 Ed. § 47-2885.10(a)(3); 22 DCMR 1909.5 and 22 DCMR 1909.6). *See DOH v. CVS Pharmacies #1335, 1344, 1343, and 1346*, OAH No. DH-I-07-D100262 (consolidated) (OAH 2007) ("First *CVS* Decision"). The undisputed facts of both cases are: after a customer drops off a prescription, medication is removed from a manufacturer's original bulk container, placed into an individual medication container, labeled with certain identifying information and segregated for customer pick up. If the customer does not return to purchase the medication, Respondent affixes a new label marked "Return to Stock" over the original label and the prescription is restocked on the shelf next to the bulk container of the same medicine. Later, if a new customer submits a prescription for the same medication, Respondent takes the medicine from the container labeled "Return to Stock," places the medication in a new container and labels the new container for the new customer. Respondent argued, at the hearing and in subsequent pleadings, that the facts of the pending case are identical to those in the First *CVS* Decision, so the Government cannot (re)argue in this case that Respondent's practices are a

violation of the law. The Government maintained at the hearing and in subsequent briefs that the Final Order issued in the First *CVS* Decision was grounded in D.C. Code, 2001 Ed. § 47-2885.10(a)(3); 22 DCMR 1909.5 and 22 DCMR 1909.6. Whereas, the Government's position in the pending case is that Respondent has violated D.C. Code, 2001 Ed. § 47-2885.10(a)(3), because Respondent's practices violate 22 DCMR 1913.2 (a different regulatory provision than that litigated in the First *CVS* Decision), as well as the fact that the individual pharmacies and the specific substances involved are different. I will address Respondent's Motion to Dismiss first.

A. RESPONDENT'S MOTION TO DISMISS

As noted above, Respondent argued that the Return to Stock violations should be dismissed according to the legal doctrines of *res judicata* and/or collateral estoppel, because I ruled in a case with nearly identical facts that Respondent's practices did not violate the cited regulations. *See* First *CVS* Decision. The Government countered by noting that its legal theory supporting the charges in the pending case has changed and, based on this change, the doctrines of *res judicata* and collateral estoppel do not apply to the consolidated cases (let alone that the facts are not actually identical). Specifically, the Government maintains that in the First *CVS* Decision, it relied on 22 DCMR 1909.5 and 1909.6 to support its charges against Respondent; whereas now it is relying on 22 DCMR 1913.2 to support it position that Respondent's practices violate the controlling regulatory scheme.

The D.C. Court of Appeals has ruled that the doctrines of *res judicata* and collateral estoppel are applicable to administrative law proceedings. *Gallothom, Inc. v. D.C. Alcoholic Bev. Control Bd.,* 820 A.2d 530 (D.C. 2003). In *Gallothom*, the Court of Appeals ruled that

> 'Res judicata bars a claim based on the same factual transaction and the same parties if an action was brought or could have been brought in a forum that has rendered a final decision on the merits.' *Herbin v. Hoeffel*, 806 A.2d 186, 193 (D.C. 2002) (citation omitted). While 'collateral estoppel, or issue preclusion, renders conclusive in the same or a subsequent action determination of an issue of fact or law when (1) the issue is actually litigated and (2) determined by a valid, final judgment on the merits; (3) after a full and fair opportunity for litigation by the parties or their privies; (4) under circumstances where the determination was essential to the judgment, and not merely dictum.' *Davis v. Davis*, 663 A.2d 499, 501 (D.C. 1995) (citation omitted).

Gallothom, Inc., 820 A.2d at 532-533.

In the First *CVS* Decision, the Government asserted that Respondent sold and dispensed controlled substances that were misbranded. The Government's premise for that assertion was the uncontested fact that in utilizing the procedures outlined above, Respondent did not record on each individual prescription container the lot number of the bulk container from which the medication was taken.[1] The Government argued that Respondent's failure to empty the un-purchased prescription into the original bulk container from which it was removed prevented Respondent from tracking, by lot number, the medications that have been dispensed and returned to stock. The Government maintained that this was a problem because, for instance, if the manufacturer recalled a medication by lot number, Respondent would not know where it had dispensed the recalled drug(s). Respondent argued that the regulations cited by the Government do not require a pharmacy to record the manufacturer's lot number on the individual prescription container and do not prohibit a pharmacy from handling controlled substances in the manner used by Respondent. *See* 22 DCMR 1913.1.

In the First *CVS* Decision, I concluded that Respondent was correct. Specifically, I decided that none of the evidence supported a conclusion that Respondent misbranded drugs by

[1] The parties use the phrases "lot number" and "manufacturer's control number" interchangeably.

restocking prescriptions that were not purchased by customers in the manner described above. Second, I concluded that the problem, if one existed at all, was not due to Respondent's restocking procedures, but rather, the fact that Respondent does not record the manufacturer's lot numbers on individual prescription containers. Whether one of Respondent's customers failed to pick up a prescription, which was then returned to stock, had no bearing on Respondent's ability (or lack thereof) to identify which customers have medication that has been recalled by the manufacturer (the problem the Government seeks to avoid). My conclusion was predicated on D.C. Code, 2001 Ed. § 47-2885.10(a)(3), 22 DCMR 1909.5 and 22 DCMR 1909.6, all of which bar the sale of misbranded pharmaceuticals. Based on these legal conclusions, I dismissed the charges against Respondent. *See* First *CVS* Decision.

In the pending cases, the Government again identified D.C. Code, 2001 Ed. § 47-2885.10(a)(3) as the applicable statutory provision on the NOI. At the outset of the November 16, 2007, hearing and in subsequent briefs, the Government argued that Respondent violated this statute by failing to adhere to 22 DCMR 1913.2, which requires pharmacies to "label[] each prepackaged container with. . . (d) The manufacturer's control number. . . ." 22 DCMR 1913.2. The Government asserted that when a pharmacist restocks the individual container of drugs onto the shelf with bulk containers (as compared to emptying the prescription bottle into the bulk container for later resale) this renders the individual container a "prepackaged container," such that Respondent is required to put the manufacturer's control number (or lot number) on the label. Respondent countered by noting that in addition to its arguments regarding *res judicata* and collateral estoppel, the fact that the Government did not identify 22 DCMR 1913.2 as controlling until the November 16, 2007, hearing violates the requirement

under local law that the NOI contain a "citation of the law or regulation alleged to have been violated." D.C. Code, 2001 Ed. § 2-1802.1(b)(2).

As noted by the Court of Appeals, the doctrine of *res judicata* "bars a claim based on the same factual transaction and the same parties if an action was brought . . . in a forum that has rendered a final decision on the merits." *Gallothom, Inc.,* 820 A.2d at 532. In the First *CVS* Decision, the Government alleged that on March 8, 2007, Respondent was prepared to sell nine different drugs which had been handled in the manner described above. However, in the pending cases, the Government alleged that on subsequent dates Respondent was prepared to sell a large number of different medications in different pharmacies in the manner described above. *See e.g.* exhibit 101. Therefore, I conclude that Respondent has failed to prove that the pending claims are "based on the same factual transaction." *Gallothom, Inc.,* 820 A.2d at 532. The doctrine of *res judicata* does not apply to these cases.

Respondent has also argued that the pending matter should be dismissed because the doctrine of issue preclusion prevents the Government from litigating "an issue of fact or law when (1) the issue is actually litigated and (2) determined by a valid, final judgment on the merits; (3) after a full and fair opportunity for litigation by the parties or their privies; (4) under circumstances where the determination was essential to the judgment, and not merely dictum." *Gallothom, Inc.,* 820 A.2d at 532-533 (citation omitted). Respondent's argument in favor of application of the doctrine of collateral estoppel is predicated on the similar factual issues involved in the First *CVS* Decision and the pending cases. The Government, while conceding that the facts of the two cases are similar, focuses its counter argument on the different, un-litigated legal theory (22 DCMR 1913.2) it seeks to have applied to the pending cases.[2]

[2] Neither party argues that the second, third or fourth prongs of this test are at issue herein.

In the First *CVS* Decision, I did rule on a nearly-identical fact pattern as that set forth herein. However, the facts at issue co not constitute the "same factual transaction," and in the pending cases the Government has articulated a different legal theory in support of its contention that Respondent's practices violate the governing regulatory scheme. Respondent's brief in support of its motion to dismiss is essentially silent in response to the Government's argument on this point. For the reasons stated herein, I conclude that the doctrine of collateral estoppel does not bar the Government from litigating the pending cases.

Respondent also argued that the Government relied on a "new," previously unidentified regulation to support its theory of liability during the November 16, 2007, hearing concerning D100273. The question is whether Respondent at this stage in the process (six months after the evidentiary hearing) has impliedly consented to adjudication of liability under the theory that Respondent's policies violate 22 DCMR 1913, as compared to 22 DCMR 1909. The test for implied consent is whether the evidence that a party contends introduced a new issue was recognized by the opposing party as "aimed at the unpleaded issue." *Adler v. Abramson,* 728 A.2d 86, 91 (D.C. 1999). *See* SCR - Civil 15(b). Additionally, any party opposing an amendment of pleadings to conform to the evidence must show actual prejudice as a result of the amendment. *Emerine v. Yancey*, 680 A.2d 1380, 1385 (D.C. 1984) (amendment is acceptable where a party did anticipate or could have anticipated the "new" issue and failed to demonstrate actual prejudice in maintaining a claim or defense).

The NOIs and the Pharmacy Inspection Reports given to Respondent in each case clearly identify the Government's legal theory and the facts the Government believes offend the

regulations.[3] *See e.g.* exhibits 100-102. Additionally, the Government's evidence and argument establish that it is operating under a theory that liability attaches pursuant to 22 DCMR 1913 (approximately six months has passed since Respondent first learned of this legal theory). During this time, Respondent has filed three post-hearing briefs on this topic and appeared before me numerous times. Beginning on November 16, 2007, Respondent has been aware of the fact that Government's liability theory was predicated on 22 DCMR 1913, not 22 DCMR 1909. Further, Respondent has not articulated any prejudice it has suffered in maintaining its defense as a result of the Government's "changed" legal theory. I conclude that the Government has complied with the notice requirements of D.C. Code, 2001 Ed. § 2-1802.1(b)(2). For all of the reasons set forth herein, Respondent's motion to dismiss is **DENIED**.

I will make certain findings based on the evidentiary record created during the November 16, 2007, hearing. However, the parties acknowledge that the basic underlying facts are grounded in company policy and the circumstances described happen in each CVS store in the District of Columbia. Based on the submissions of the parties and accepting the allegations of both parties as fact, as well as the entire record herein, I make the following findings of fact and conclusions of law.

B. FINDINGS OF FACT

1. On June 27, 2007, Janis Jackson, Pharmacist for the Department of Health, inspected Respondent's store number 2174, located at 4555 Wisconsin Ave., NW. Exhibit 100. During this inspection, Ms. Jackson discovered twenty-eight medications that she determined were

[3] NOIs D100291, D100304, D100305 and D100309 all cite D.C. Code, 2001 Ed. § 47-2885.10(a)(3) and 22 DCMR 1909 as the governing regulations. Of course, 22 DCMR 1909 is the regulation unsuccessfully relied upon by the Government in the First *CVS* Decision. For the reasons set forth herein, I conclude that this reference on the NOIs is not dispositive.

misbranded for one or more reasons. Exhibit 101. Specifically, the individual medication containers did not have either: i) an expiration date on its label; ii) a manufacturer's lot number on its label; or iii) any label at all. Exhibit 101.

2. Prescription drugs are sold in one of two containers in the District of Columbia: one is in the manufacturer's original container; and the other is in a clean, new container. 22 DCMR 1912.2. When the controlled substance is sold in a manufacturer's original container, the container is frequently called "unit-of-use packaging." Exhibit 210A, page 1. These containers may be bottles or blister packs and "contain enough product for patients' use for a specified time interval." *Id*. It is common for States to require the drug manufacturer to imprint the drug's lot number on the unit-of-use container. Exhibit 210A, page 2, table 1. When a pharmacist repackages a drug from the manufacturer's original bulk container into individual medication containers, the new container is called a "prepackaged container." 22 DCMR 1912.8. *See also* exhibits 210, paragraph 7-8, 210A, page 1.[4]

3. The medication at issue in these cases has been packaged into individual containers by Respondent's pharmacist(s) for dispensation to customers with appropriate prescriptions. After prepackaging the medication, the pharmacist affixes a label to the individual container that does not include the manufacturer's control number. If, after submitting a prescription, the customer never returns to the store to actually purchase the medication, Respondent's policy is for

[4] Exhibits 210A identified two types of "prepackaging." One is when "larger quantities of bulk products from a manufacturer's original commercial container are repackaged into small quantities consistent with commonly prescribed dosage regimens." Exhibit 210A, page 1. The other is medications "repackaged for multichannel distribution, these products are pre-packaged by facilities that dispense them directly to patients . . . ." *Id*. Respondent submitted an affidavit from David Brushwood, a lawyer and pharmacist, as an exhibit. Exhibit 210. In his affidavit, Mr. Brushwood declares that these definitions of "prepackaging" mean that the "prepackaged drugs are prepared in quantities in advance for dispensing for *as yet unidentified patients*." Exhibit 210, paragraph 8 (emphasis added). Mr. Brushwood does not explain how or why he reaches that conclusion. Either way, local regulations do not draw such distinctions. *See* 22 DCMR 1912, 1913.

pharmacists to affix labels marked "Return to Stock" on the individual medication container and place the still-filled individual container on the shelf near the bulk container for the medication in question. Exhibits 204, 205. Respondent's policy is not to remove the original label secured to the container when the prescription was filled for the customer prior to putting the Return to Stock label on the container.

4. If a new customer comes into the store and submits a prescription for the exact same medication as an individual medication container that has a Return to Stock label, the pharmacist packages the medication into a new individual container and attaches a new label to the individual medication container. This new label does not include the manufacturer's control number.

5. Respondent's policy is for pharmacists to use a computer system to generate a Return to Stock label. This computer system "[a]utomatically places a 6 month expiration date on . . ." a Return to stock label, unless the actual expiration date is shorter, in which case the actual expiration date is used. Exhibit 209. Respondent has implemented this policy to ensure that all Return to Stock prescription medications are actually disposed of on or before the manufacturer's expiration date.

6. It is also Respondent's policy to send expired (or recalled) controlled substances to a third-party vendor, Capital Returns, Inc., for disposal. Exhibits 206, 207, 208.

7. When a drug manufacturer or distributor determines that a drug recall is warranted, it is required to provide the Food and Drug Administration ("FDA") with a "recall submission." Exhibit 210B, page 2. Pursuant to guidance issued by the FDA, the recall submission should include "lot numbers." Exhibit 210B, page 3. CVS policy recognizes that recalls track drug lot

numbers. Exhibit 208. Additionally, when the drug manufacturer/distributor moves forward with a recall, written notification is required. Exhibit 210B, page 7. According to the FDA, this written notification should include the "lot number." *Id*.

8. The FDA categorizes drug recalls by "class." A Class I recall occurs when the FDA determines that there "is a reasonable probability that use of the product will cause SERIOUS ADVERSE HEALTH CONSEQUENCES OR DEATH." Exhibit 208 (emphasis in original). In these cases, the FDA mandates that Respondent contact customers who have purchased the recalled medication and request that any unused portions be returned to the pharmacy. Exhibits 208, 210B. Respondent's policy specifically instructs staff to "run a computer report listing all those patients who have received that medication during the period in question." Exhibit 208. Staff is then instructed to call these customers, but to "BE CAREFUL NOT TO ALARM THE PATIENT." Exhibit 208 (emphasis added). In response to a Class I recall, Respondent's policy also requires pharmacists to "PULL all recalled merchandise off the shelf immediately . . . [which] includes product with the identified lot # and expiration date and all Return to Stock vials regardless of the RTS label's expiration date." Exhibit 208 (emphasis in original). The same recall policy requires Respondent to "offer to make an exchange for any unused portion with a product with a lot number not affected by the recall." Exhibit 208.

C. DISCUSSION AND CONCLUSIONS OF LAW

The Government alleged that Respondent violated D.C. Code, 2001 Ed. § 47-2885.10(a)(3) by offering for sale misbranded drugs. The Government maintains that once Respondent's pharmacist affixes a Return to Stock label on a filled prescription in an individual medication container and places the container on the shelf with bulk medications until a new customer

presents a prescription for the same medication, the individual medication container becomes a "prepackaged" container subject to the regulatory requirement that pharmacies put the manufacturer's lot number on the label. 22 DCMR 1913.2. Respondent denies that the individual medication containers are converted into prepackaged containers by the acts described herein and denies that the Return to Stock process is governed by 22 DCMR 1913.2.

As set forth above, the Government maintains that Respondent's practices violate the regulations controlling the dispensation of prepackaged containers, because the new prescription labels are not printed with the manufacturer's lot number.[5] 22 DCMR 1913.2(d). Respondent argues that the pertinent regulations do not require a lot number be placed on the prescription label (22 DCMR 1913.1) and, that the act of returning un-purchased prescriptions in individual containers to stock (as compared to returning the medication to a bulk container) and then placing it in new containers does not transform the prescription in to "prepackaged" drug. 22 DCMR 1912.8. Thus, Respondent maintains that its practice of returning un-purchased medication to the shelf with a Return to Stock label comports with the governing regulations.

The "primary and general rule of statutory construction is that the intent of the lawmaker is to be found in the language that he has used." *Peoples Drug Stores v. District of Columbia*, 470 A.2d 751, 754 (D.C. 1983) (*en banc*). The court must first look to the plain meaning of the statute, construing words, "according to their ordinary sense and with the meaning commonly

[5] The Government claims that including the manufacturer's lot number on the label ensures that in the event of a manufacturer's recall of a medication (which occurs by lot number and expiration date), the recalled medication can be traced to the individual purchaser (who can be notified personally of the recall). Thus, it is confusing that the Government argues that the regulatory obligation to put the lot number on an individual medication container is limited to those circumstances when a medication was returned to stock. The Government's suggested interpretation of the rules means that the only consumers who will benefit from the proposed labeling requirement will be the lucky persons who buy medication that was returned to stock. However, the average consumer, who buys medications that were drawn directly from bulk containers, will not be protected by the regulatory umbrella under the Government's theory.

attributed to them." *Davis v. United States,* 397 A.2d 951, 956 (D.C. 1979). "The literal words of [a] statute, however, are not the sole index to legislative intent, but rather, are to be read in the light of the statute taken as a whole, and are to be given a sensible construction …." *District of Columbia v. Gallagher*, 734 A.2d 1087, 1091 (D.C. 1999) [*quoting Metzler v. Edwards*, 53 A.2d 42, 44 (D.C. 1947)]. Courts generally construe administrative regulations by the same rules that apply to the interpretation of statutes. *In re R.F.H.*, 354 A.2d 844, 845 n.2 (D.C. 1976); *KCMC Inc. v. FCC*, 600 F.2d 546, 549 (5th Cir. 1979); *Rucker v. Wabash R.R.*, 418 F.2d 146, 149 (7th Cir. 1969); C. Sands, SUTHERLAND, STATUTORY CONSTRUCTION § 31.06 (4th ed. 1972).

The regulation concerning the packaging of controlled substances establishes that:

> 1912.2. A pharmacy shall dispense drugs or medical devices in new and clean containers or in the manufacturer's original container or package.
>
> 1912.8. A pharmacy shall exercise direct personal supervision of the prepackaging of drugs.
>
> 1912.9. A pharmacy shall keep a log of drugs that have been prepackaged under a pharmacist's supervision. The log must contain the following information:
>
> * * *
>
> (d) The lot and control number of the drug;
>
> * * *

22 DCMR 1912.2, 1912.8, and 1912.9(d) (emphasis added).

The regulations governing the labeling of prescription drugs require:

> A container in which a prescription drug or device is sold or dispensed must bear a label containing the following information:
> (a) The name, address, and telephone number of the pharmacy;
> (b) The name of the patient;
> (c) The name of the prescriber;
> (d) Directions for usage;
> (e) The serial number of the prescription and the date filled;

> (f) The generic, chemical, or brand name and strength of the drug dispensed. . .; and
> (g) The expiration date of the product. . . .

22 DCMR 1913.1.

> A pharmacy shall be responsible for labeling each *prepackaged container* with the following information:
>
> * * *
> (d) The manufacturer's control number;
>
> * * *

22 DCMR 1913.2(d) (emphasis added).

As it relates to the packaging of medications, the regulations authorize only two ways for a pharmacy to dispense controlled substances, either in new packaging or the manufacturer's original container. 22 DCMR 1912.2. The regulations then note that whenever a controlled substance is being dispensed in something other than the manufacturer's original container, the "pharmacy shall exercise direct personal supervision of the prepackaging of drugs." 22 DCMR 1912.8. The pharmacy is also responsible for keeping "a log of drugs that have been prepackaged under a pharmacist's supervision." 22 DCMR 1912.9. I have concluded that when the regulators used the word "prepackaged," their intent was to identify a drug that is repackaged by the pharmacist before it is sold to the public.[6] This construction of the regulations is supported by the requirements set forth in the next regulation (22 DCMR 1913). Specifically, this regulation requires that "each prepackaged container" be labeled with certain information. 22 DCMR 1913.2.

[6] My construction of the regulations takes into consideration that some controlled substances are packaged by the manufacturer in retail size containers, as compared to just in bulk containers (*e.g.* "unit-of-use" containers). *See* exhibit 210A, page 1.

Thus, the regulations initially declare that there are only two ways to sell medications, in a new container or the manufacturer's original package. Then, in the same sub-section the regulations require a pharmacy to monitor "the prepackaging of drugs" (22 DCMR 1912.8) under a "pharmacist's supervision," (22 DCMR 1912.9). And, in the next section, the regulations set forth two labeling requirements for "dispensed drugs." 22 DCMR 1913. Initially, the regulations establish the minimum requirements for a label that is affixed to a "dispensed drug." 22 DCMR 1913.1. This regulatory provision does not require inclusion of the manufacturer's lot number on the label. Respondent relies on this provision in support of its contention that it is not obligated to put the lot number on the labels of dispensed drug. However, the regulation goes on to declare, as noted above, that a pharmacy is responsible for labeling each "prepackaged container" with the "(d) manufacturer's control number." 22 DCMR 1913.2.[7]

While the regulations are not a paradigm of clarity, I conclude that the two provisions can be harmonized. The regulators are instructing pharmacists that when a pharmaceutical is being prepared for sale by prepackaging the medication in a "new and clean" container, a pharmacy has to supervise this "prepackaging of drugs." 22 DCMR 1912.8. The regulators are also instructing pharmacists that medications placed in a "prepackaged container" must carry a label with the manufacturer's control number. 22 DCMR 1913.2. Concomitantly, when drugs are sold in manufacturer's original containers, such as unit-of-use containers, pursuant to 22 DCMR 1912.2, the manufacturer's lot number is not required on the label affixed by the pharmacy

[7] Respondent's exhibit 210A, page 2, Table 1, implies that all manufacturer's original containers designed for retail sale have identifying information that allows for the tracking of medications whenever required. The pertinent regulations establish this requirement by setting minimum data required on all labels (customer and store specific information) (22 DCMR 1913.1) and additional information required on labels affixed to prepackaged containers (22DCMR 1913.2).

because the manufacturer has imprinted lot numbers on the container. 22 DCMR 1913.1. *See also* exhibit 210A, page 2, table 1. Otherwise, the end result would be that the regulations establish only two containers in which controlled substances may be dispensed (a "new and clean container" or the "manufacturer's original container"), but then, in a provision designed to ensure pharmacist control over the movement of controlled substances, create a third means for packaging medications (a prepackaged container). This outcome is not consistent with the plain meaning of the regulations.

While Respondent takes issue with the Government's characterization of two of the twenty-eight medications identified on the Government's list of misbranded drugs, there is no dispute that Respondent does not record the manufacturer's lot or control number (as noted above the parties use these words as if they are the same number) on the labels it adheres to individual, prepackaged medication containers. Exhibit 101. Further, if a drug is recalled, Respondent's policy is for the pharmacist to "PULL all recalled merchandise off the shelf immediately . . . . [which] includes product with the identified lot # and expiration date and all Return to Stock vials regardless of the R[eturn] T[o] S[tock] label's expiration date." Exhibit 208 (emphasis in original). Respondent's policy specifically instructs staff to "run a computer report listing all those patients who have received that medication during the period in question." Exhibit 208. Staff is then instructed to call these customers, but to "BE CAREFUL NOT TO ALARM THE PATIENT." Exhibit 208 (emphasis added). Respondent also offers to exchange "any unused portion [of a recalled drug] with a product *with a lot number* not affected by the recall." Exhibit 208 (emphasis added).

Clearly, the recall and exchange of controlled substances is driven, at least in part, by the manufacturer's control number. Exhibit 210B. In spite of that, as written, Respondent's policy

is to contact ALL customers who have purchased the recalled medication, as compared to just those customers who purchased the specific lot(s) actually recalled by the FDA. This policy is illogical and unduly burdensome to the consumer. Respondent, recognizing that a recall will understandably frighten customers, tells staff to "be careful not to alarm the patient." However, can anything be more frightening than receiving a call from your pharmacist to say that your medication may have been recalled because ongoing usage will probably cause "serious adverse health consequences or death," but the pharmacist is not certain whether you took the recalled medication and/or whether you require urgent medical attention to avoid death? It is not clear that Respondent's practices actually comport with this policy. Additionally, Respondent's practice of not listing the manufacturer's control number on the label attached to each customer's medication container appears to actually create a health risk in that it prevents Respondent from safely and effectively managing an FDA-ordered medication recall and protecting consumer health.

Based on my construction of the regulations, I conclude that the requirements concerning the labeling of "prepackaged containers," in the circumstances discussed herein, apply to the medications dispensed by Respondent. These requirements include listing the manufacturer's control number. 22 DCMR 1913.2(d). By failing to include the manufacturer's control number on the label, Respondent is selling misbranded drugs in violation of D.C. Code, 2001 Ed. § 47-2885.10(a)(3). I conclude Respondent is **LIABLE** for all charges concerning the return to stock of pharmaceuticals in these NOIs.

Respondent violated D.C. Code, 2001 Ed. § 47-2885.10(a)(3), as charged in the NOIs. The violation is a Class 1 infraction punishable by a maximum $2,000 fine for each first offense.

16 DCMR 3201.1(c); 16 DCMR 3615(f).[8] The Government has requested a $2,000 fine for each violation for a total fine in the amount of $12,000. I hereby impose a $12,000 fine.

III. DISMISSAL OF DH-I-07-D100292

The parties have agreed that D100292, an NOI issued after Respondent filed an untimely plea to NOI D100274, should be dismissed with prejudice. I concur.

A. FINDINGS OF FACT

1. On July 25, 2007, the Government served NOI D100274 on Judith Sanders, Pharmacist, One CVS Drive, Woonsocket, RI 02895. In an earlier case, the parties agreed, and this administrative court ordered, that NOIs shall be served on Susan Delmonico, One CVS Drive, Woonsocket, RI 02895. On October 17, 2007, this administrative court served a Notice of Default on Respondent at its Woonsocket, RI address. However, the Notice of Default also was not sent to Ms. Delmonico's attention. The Government issued the second NOI D100292 on November 8, 2007.

2. Judith Sanders does not work for Respondent in Woonsocket, RI. Rather, Ms. Sanders works, or did at the time, at the CVS pharmacy located at 660 Rhode Island Ave., NE, Washington, DC. By the time that the NOI made it to Ms. Delmonico, Respondent's opportunity to file its plea timely had expired.

[8] If I were to conclude that the pertinent authority for assessing the fine was 22 DCMR 1913, the associated maximum fine is still $2,000 for each first offense. 16 DCMR 3616.1(l).

B. CONCLUSIONS OF LAW

The Civil Infractions Act, D.C. Code, 2001 Ed. §§ 2-1802.02(f) and 2-1802.05, provides that there must be "good cause" for a respondent's failure to answer a Notice of Infraction within 20 days of the date of service by mail. If there is not, the statute requires that a penalty equal to the amount of the proposed fine must be imposed. D.C. Code, 2001 Ed. §§ 2-1801.04(a)(2)(A) and 2-1802.02(f). If the respondent fails to answer a second Notice of Infraction without good cause, the party is in default and the penalty doubles. D.C. Code, 2001 Ed. §§ 2-1801.04(a)(2)(B) and 2-1802.02(f). Respondent has explained that neither the original NOI (D100274), nor the Notice of Default served by this administrative court were served on Respondent in the manner ordered by this administrative court. Therefore, Respondent was hampered in its efforts to file timely its plea. I accept Respondent's explanation for its failure to respond timely and conclude that Respondent had good cause for that failure. Accordingly, I dismiss the second NOI D100292 and the statutory penalty of $1,000 shall not be applied.

IV. ORDER

Therefore, based on the entire record herein, it is this 13th day of June 2008

ORDERED that Respondent's exhibits 206-209 are admitted into evidence; it is further

ORDERED that NOI D100292 is hereby **DISMISSED WITH PREJUDICE**; it is further

ORDERED that Respondent CVS is **LIABLE** for violating D.C. Code, 2001 Ed. § 47-2885.10(a)(3), as alleged in NOI D100273, D100279, D100291, D100282, D100304, and D100305; it is further

ORDERED that Respondent shall pay a fine in the amount of **TWELVE THOUSAND DOLLARS ($12,000**) in accordance with the attached instructions within twenty (20) calendar days of the date of mailing of this Order (15 calendar days plus 5 days for service by mail pursuant, to D.C. Code, 2001 Ed. §§ 2-1802.04 and 2-1802.05); it is further

ORDERED that, if Respondent fails to pay the above amount in full within 20 calendar days of the date of mailing of this Order, by law, interest shall accrue on the unpaid amount at the rate of 1½ %, or **ONE HUNDRED EIGHTY DOLLARS** (**$180**), per month or portion thereof, beginning with the date of this Order, pursuant to D.C. Code, 2001 Ed. § 2-1802.03(i)(1); it is further

ORDERED that failure to comply with the attached payment instructions and to remit a payment within the time specified will authorize the imposition of additional sanctions, including the suspension of Respondent's licenses or permits, pursuant to D.C. Code, 2001 Ed. § 2-1802.03(f), the placement of a lien on real or personal property owned by Respondent, pursuant to D.C. Code, 2001 Ed. § 2-1802.03(i), and the sealing of Respondent's business premises or work sites, pursuant to D.C. Code, 2001 Ed. § 2-1801.03(b)(7); it is further

ORDERED that the appeal rights of any person aggrieved by this Order are stated below.

June 13, 2008

/SS/
Jesse P. Goode
Administrative Law Judge